K053228

THERICS, LLC.
115 CAMPUS DRIVE
PRINCETON, NJ 08540
TELEPHONE: 609-514-7200
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JAN 3 1 2006

THERICS

510(k) SUMMARY

Therics' TheriGraft™ Bone Void Filler

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter's Name:

Sunil Saini
Telephone: 609.514.7200 x7262 or 609.514.7200 (main)
Facsimile: 609.514.0255
Contact Person: Sunil Saini

Date Prepared: November 1, 2005

Name of Device and Name/Address of Sponsor

TRADE/PROPRIETARY NAME OF DEVICE:
TheriGraft™ TCP Putty Bone Void Filler

ADDRESS:
115 Campus Drive
Princeton, New Jersey 08540

Common or Usual Name:
Bone Void Filler.
Synthetic Bone Void Filler.
Synthetic Cancellous Bone Void Filler.
Bone Graft Substitute.
Synthetic Bone Substitute.
Synthetic Cancellous Bone Substitute.

Classification Name
Bone Void Filler

Predicate Device
Orthovita's Vitoss™

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Intended Use / Indications for Use

TheriGraft™ TCP Putty Bone Void Filler is indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma and is intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e. the extremities, spine and pelvis). TheriGraft™ putty creates a network within the defect site that resorbs during healing and is replaced by bone.

Technological Characteristics and Substantial Equivalence

The TheriGraft™ Bone Void Filler is constructed of synthetic β-tricalcium phosphate granules (0.1 – 0.4 mm diameter) in a poloxamer based carrier.

Pre-clinical performance testing conducted on TheriGraft™ and Vitoss™ in a canine animal model according to indication yielded similar results based on tissue reaction, bone ingrowth, residual material, and mechanical testing. TheriGraft™ bone void filler has the same intended use and indications, the same or similar principles of operation and technological characteristics, and equivalent performance in an appropriate animal model. Therefore, Therics' TheriGraft™ Bone Void Filler is substantially equivalent to the predicate device (see Table 1).

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Table 1: TheriGraft™ & Vitoss™ SE and Comparison Chart

Characteristics or Attributes	TheriGraft™ (NEW)	Vitoss ™ K994337	Comments
Indications for Use	Indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma. TheriGraft™ may be used with autogenous bone marrow	Indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma. Vitoss may be used with autogenous bone marrow	Same
Intended Use	Intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e., the extremities, spine and pelvis).	Intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e., the extremities, spine and pelvis).	Same.
Labeling	See Indications for Use and Intended Use.	See Indications for Use and Intended Use.	SE.
Target Population	Patients with osseous defects surgically created or resulting from trauma.	Patients with osseous defects surgically created or resulting from trauma.	Same.
Design	Porous trabecular structures similar to cancellous bone. Approximately 0.1 – 0.4 mm granules.	Porous trabecular structures similar to cancellous bone. 1 – 4 mm granules.	Similar internal structures for TheriGraft & Vitoss. Granule dimensions are different.
Materials	Calcium salt; β-tricalcium phosphate mineral phase in poloxamer carrier.	Calcium salt; β-tricalcium phosphate mineral phase.	Same.
Performance	Pre-clinical study to demonstrate performance characteristics.	Pre-clinical study to demonstrate performance characteristics.	SE.
Sterility	Gamma irradiation.	Gamma irradiation.	Same.
Biocompatibility	Product tested according to ISO 10993, Biological Evaluation of Medical Devices.	Unknown.	Same.
Chemical Safety	Product tested according to ISO 10993, Biological Evaluation of Medical Devices.	Unknown.	Same.
Anatomical Sites	Osseous defects not intrinsic to the stability of the bone structure.	Osseous defects not intrinsic to the stability of the bone structure.	Same.
Where Used: Hospital, home, ambulance, etc.	Hospital or Health Care Practitioner's surgical suite.	Hospital or Health Care Practitioner's surgical suite.	Same.
Design Control	Design Controls: Verification & Validation utilized.	Unknown.	SE.

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Attachment - 12

Indications for Use Form

510(k) Number (if known):

Not assigned at this time

Device Name:

TheriGraft™ TCP Putty Bone Void Filler

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2006

Sunil Saini, Ph.D.
Director, Biomaterials
THERICS, LLC.
115 Campus Drive
Princeton, New Jersey 08540

Re: K053228
Trade/Device Name: TheriGraft™ TCP Putty Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: November 16, 2005
Received: November 21, 2005

Dear Dr. Saini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053228

Device Name: **Therigraft™ TCP Putty Bone Void Filler**

Indications For Use:

TheriGraft™ Bone Void Filler is indicated for use in filling the gaps or voids of osseous defects surgically created or resulting from trauma and is intended for treatment of osseous defects not intrinsic to the stability of the bone structure. The product is intended for use in defects of the skeletal system (i.e. the extremities, spine and pelvis). TheriGraft™ putty creates a network within the defect site that resorbs during healing and is replaced by bone.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K053228